

REMARKS/ARGUMENTS

Applicants acknowledge with appreciation the withdrawal of the finality of the previous Office Action. Applicants also acknowledge with appreciation the withdrawal of the previous objection to claim 68, the rejections of claims under 35 U.S.C. § 112, first paragraph, the rejection of claims under 35 U.S.C. § 102, and the rejection of claims under 35 U.S.C. § 103.

Claims 68, 69, 71, and 75-79 are pending in the application. Claims 68 and 69 have been amended. Support for the amendments can be found in the specification and original claims, as more particularly set forth below. No new matter has been added by way of amendment. Reexamination and reconsideration of the claims are respectfully requested.

The Objection to Claim 68 Should Be Withdrawn

The Office Action (April 6, 2004, page 3, #10) has objected to claim 68 for certain specified reasons. Claim 68 has been amended in accordance with the suggestions in the Office Action; accordingly, the objection has been obviated by amendment and should be withdrawn.

The Rejection of Claims Under 35 U.S.C. §112, Second Paragraph, Should Be Withdrawn

The Office Action (April 6, 2004, page 4, #11) has rejected claims 68, 69, 71, and 75-79 as being indefinite because “vegetative storage protein (vsp) is a generic term for these types of proteins. If only making mutations in SEQ ID NO:1 is intended, such limitation in the claims is required for clarity.” Applicants respectfully traverse this rejection and note that the rejection indicated only that clarification was required, not that the claims must be limited to making mutations in SEQ ID NO:1.

The present claims are drawn to a method for altering the amino acid composition of a vegetative storage protein which is a VSP β . The claimed method is not limited to only making mutations in SEQ ID NO:1 but rather encompasses methods for altering the amino acid composition of any vegetative storage protein which is a VSP β . Applicants note that although VSP β is a generic term readily understood by those of skill in the art, it encompasses a very narrow genus. Having thus clarified that the claimed method is not limited to only making

mutations in SEQ ID NO:1, Applicants respectfully request that this rejection of the claims be withdrawn.

The Office Action (April 6, 2004, page 4, #12) has rejected claims 68, 69, 71, and 75-79 as indefinite because “it is unclear if such maintenance [of native conformation] is a clear limitation of the claimed methods.” Applicants respectfully traverse this rejection and note that the claims are now narrowly drawn to a method for altering the amino acid composition of a vegetative storage protein which is VSP β .

Applicants note that the claims had previously been amended to address a rejection under 35 U.S.C. §112, first paragraph, in the Office Action dated October 15, 2003 (page 7, #15), in which it was suggested that the claims be amended “so that, while the conformation of the altered protein is considered, it need not be determined.” Applicants amended the claims in accordance with this suggestion in the amendment filed on December 15, 2003.

Applicants have now further amended independent claims 68 and 69 to specify that the antibodies of the claims, which recognize the native conformation of the protein, also bind to the engineered protein. The remaining claims are dependent on or incorporate the limitations of claim 68 or claim 69 and therefore have also been amended as described. Support for these amendments can be found in the specification, for example, on page 2. In the Office Action dated October 15, 2003 (page 7, second paragraph), it was acknowledged that “a set of antibodies, if large enough, would be able to identify VSP proteins ‘substantially retaining native conformation.’” The claims now require that the antibodies bind both the native protein and the engineered protein; one of skill in the art will appreciate that these additional limitations essentially require that the engineered protein will substantially retain the native conformation. Accordingly, in view of these amendments, Applicants respectfully request that this rejection be withdrawn.

The Office Action (April 6, 2004, page 5, #13) has rejected claims 68, 69, 71, and 75-79 for being indefinite due to language characterized as “redundant and wordy.” Independent claims 68 and 69 have been amended in accordance with the suggestion to remove “the ‘capable’

phrase.” The remaining claims are dependent on or incorporate the limitations of claim 68 or claim 69 and therefore have also been amended as described. Accordingly, Applicants respectfully request that this rejection of the claims be withdrawn.

The Rejection of Claim Under 35 U.S.C. §112, First Paragraph, Should Be Withdrawn

The Office Action (April 6, 2004, page 5, #14) has rejected claims 68, 69, 71, and 75-79 as failing to comply with the written description requirement because “[t]he concepts of percent change are not supported in the specification as originally filed....”

As suggested in the Office Action, independent claim 68 has been amended to specify that the amino acid changes alter the content of nutritionally essential amino acids by at least 10%, and independent claim 69 has been amended to specify that nutritionally essential amino acids are increased to represent at least 5% to 10% of the total amino acid content of the engineered VSP β . The remaining claims are dependent on or incorporate the limitations of claim 68 and 69 and therefore have also been amended as described. Support for these amendments can be found in the specification, for example, on page 7, lines 25-31. Accordingly, Applicants respectfully request that this rejection of the claims be withdrawn.

The Office Action (April 6, 2004, page 6, #15) has rejected claims 68, 69, 71, and 75-79 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description “based on two concepts: (1) the lack of an upper boundary on the alteration in the protein’s structure and (2) set of antibodies that recognize native conformation.” Applicants respectfully traverse this rejection.

With regard to the second concept, Applicants note that the claims have been amended and no longer contain the limitation that was this second basis for the written description rejection. The claims now require that the set of antibodies binds to the native protein and also binds to the engineered protein, which is supported in the specification, for example, on page 2. Accordingly, Applicants respectfully submit that this basis for the rejection no longer exists.

With regard to the first concept, Applicants respectfully submit that the claims meet the written description requirement without the addition of an explicit upper boundary on the

alteration in the protein's structure. The claims are drawn to a method for altering the amino acid composition of a vegetative storage protein which is VSP β comprising introducing amino acid changes into VSP β and assessing the conformation of the engineered protein based on its ability to bind with a set of antibodies that bind to native VSP β . Applicants have provided a working example showing alteration of the amino acid content of VSP β by at least 8.25% (see specification page 19) and further showing that this engineered protein was bound by antibodies that also bound the native protein. The Office Action acknowledges that "this example is adequate written description of a method that increases the methionines in VSP β by a limited amount, for example, about 10%...." Applicants agree with this conclusion.

However, the Office Action goes on to conclude that "this example is not adequate description for a method that changes the amino acid content by as much as 90 or even 100%." Applicants respectfully disagree with the conclusion that the example that satisfies the written description requirement for a particular increase in amino acid content fails to satisfy the requirement for a greater increase in amino acid content. One of skill in the art will appreciate that the steps of the claimed method are performed in the same way whether the amino acid content of the protein is changed by a small amount or by a larger amount. Because the steps of the method are performed in the same way regardless of the amount of change in the amino acid content, an example that describes the method for one amount of change also describes the method for another amount of change.

Moreover, the amended claims require that the conformation of the engineered protein is assessed based on its ability to bind with a set of antibodies that bind to the native protein. It is expected that some modifications of the native protein will produce engineered proteins that will fail to bind with the set of antibodies, and the frequency of engineered proteins that fail to bind with the set of antibodies is expected generally to increase as the amount of modification to the native protein increases. Therefore, large changes to the amino acid content would be expected to produce mostly engineered proteins that would fail to bind with the set of antibodies.

However, the steps of the method are still performed in the same way regardless of the amount of change in the amino acid content. Therefore, the steps of the method are necessarily described by the provided working example.

For these reasons, Applicants respectfully submit that the rejection of claims for lack of written description should be withdrawn.

CONCLUSION

In view of the above amendments and remarks, Applicants submit that the rejections of the claims under 35 U.S.C. §§112, first and second paragraphs, 102(b), and 103(a) are overcome. Applicants respectfully submit that this application is now in condition for allowance. Early notice to this effect is solicited.

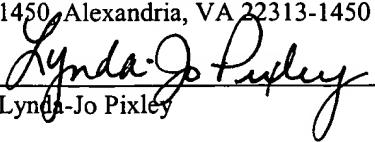
If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject Application, the Examiner is invited to call the undersigned.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,



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